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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,940	11/06/2000	Richard M. Fike	0942.4290006/RWE/BJD	7464

7590

02/11/2003

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/705,940

Applicant(s)

FIKE, RICHARD M.

Examiner

David A Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15, 16, 18-29, 31-34 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15, 16, 18-29, 31-34 and 36-39 is/are rejected.
- 7) ☒ Claim(s) 40-43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 10.
- ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Receipt is acknowledged of a reply, filed November 18, 2002 as Paper No. 9, to the previous Office Action. Amendments were made to the claims. In addition, claims 11-14, 17, 30 and 35 were cancelled and new claims 40-43 were added.

Claims 1-10, 15, 16, 18-29, 31-33 and 36-43 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 5, mailed June 17, 2002, that is not addressed in this action has been withdrawn.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 24, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Information Disclosure Statement***

The information disclosure statement filed on November 18, 2002 in Paper 6, has been considered, and a signed and initialed copy is included with this Office Action. In addition, the information disclosure statement filed on January 24, 2003 has been considered, and a signed and initialed copy is included with this Office Action.

### ***Drawings***

The drawings have been accepted by the Draftsperson.

### ***Claim Objections***

Claims 15, 19, 21, 23, 25-28, 31 and 40-43 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be recited in the alternative and cannot be dependent on a multiply dependent claim. See MPEP § 608.01(n). However, since claims 15, 19, 21, 23, 25-28 and 31 had been previously treated on the merits, those claims are examined in the instant Office Action. However, claims 40-43 had not been previously treated on the merits, and are not examined in the instant action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15, 16, 18-29, 31-34, and 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Fike *et al.* (WO 98/36051, as IDS reference AO4; henceforth Fike; see entire document).

Fike teaches a method for producing nutritive media comprising media supplements and buffers in a dry powder, followed by sterilization of the powder with gamma-rays and packaging of the powder (see page 6, lines 9-19). The media can be bacterial media, yeast media, plant culture media or animal cell culture media (see page 6, lines 21-23). Supplements for the media include powdered sera from animals, plants, etc., cytokines and growth factors, other proteins, vitamins, amino acids, co-factors, lipids, extracts of animal tissues or glands, and buffers (see page 6, line 25 to page 7, line 26). The buffers are chosen so that, upon reconstitution of the dry powder in a solvent of interest, the media automatically adjusts to a particular pH without the use of a pH adjusting agent such as an acid or a base (see page 20, lines 3-26). Buffers that would satisfy this requirement are well-known in the art, and include buffer salts such as sodium phosphate (mono- and dibasic), potassium phosphate (mono- and dibasic), sodium bicarbonate (mono- and dibasic), etc. Fike also teaches methods of using the media to culture cells (bacteria, yeast, animal, etc.), comprising reconstituting the media compositions of the above method in a solvent such as water or serum, and contacting cells with the solution under conditions that are favorable for growth of the cell (see page 8, lines 22-26). Particular cells that can be used in the method are animal/human cells, including normal, transformed diseased, etc. cells (see page 8, line 22 to page 9, line 5). Fike also teaches kits for use in the above process of culturing cells

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comprising packaging the media, and in some embodiments including the dried cells for culturing (see page 8, lines 6-11).

Fike does not specifically teach using sodium bicarbonate that does not liberate CO<sub>2</sub> upon storage (as per claim 9 of the instant invention). However, sodium bicarbonate that does not liberate CO<sub>2</sub> must have been used by Fike because the invention as taught by Fike could not be practiced if carbon dioxide was liberated in the packaged media. Fike requires that the powdered media be sterilized by gamma irradiation. The accumulation of carbon dioxide in an enclosed package would result in a build up of pressure, eventually leading to an explosion of the container, thereby comprising the sterility of the dry powder and counteracting a distinct step in the process as taught by Fike. Hence the teachings of Fike anticipate the claims of the instant invention.

*Allowable Subject Matter*

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
February 6, 2003

DAVID GUZO  
PRIMARY EXAMINER  
